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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Page

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of

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### Complete if Known

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Nichols, Christopher J.
Attorney Docket Number	020167-000120US

### U.S. PATENT DOCUMENTS

Examiner	Cite No.	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
CSN	AA	US-5,422,110	06/06/1995	Potter et al.	
CSN	AB	USPN 10/054,873	n/a	Gan	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>2</sup> (if known)				
CSN	AC	EP	0 645 454	A2	03/29/1995	Lunin et al.		
CSN	AD	WO	96/23888	A1	08/08/1996	G.D. Searle & Co		
CSN	AE	CA	1,341,211		03/27/2001	Hoechst Aktiengesellschaft		

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
CSN	AF	BIOLOGICAL DATABASE, Accession number: 100407207028. Samuelsson et al., 1994, "Enhanced <i>in vitro</i> refolding of insulin-like growth factor I using a solubilizing fusion partner," <i>Biochemistry</i> 33(14):4207-4211 (abstract)	
CSN	AG	BIOLOGICAL DATABASE, Accession number: P00190700705120. Klappa et al., 1997, "Interactions between protein disulphide isomerase and peptides," <i>European Journal of Biochemistry</i> 248(1):37-42 (abstract)	

Examiner Signature	<i>Gillie</i>	Date Considered	9/11/2003
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 3

**Complete if Known**

Application Number	09/423,100
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Filing Date	December 11, 2000
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First Named Inventor	Gan, Zhong-Ru
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Art Unit	1647
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Examiner Name	<del>Saeed, Christine d</del>
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Attorney Docket Number	020167-000120US
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## U.S. PATENT DOCUMENTS

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3/6/2003

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 3

## Complete if Known

Application Number 09/423,100  
Filing Date December 11, 2000  
First Named Inventor Gan, Zhong-Ru  
Art Unit 1647  
Examiner Name Seoud, Christine J.  
Attorney Docket Number 020167-000120US

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## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

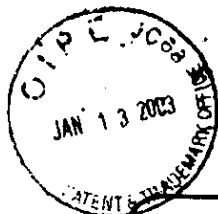
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
CSU	AG	U. Shinde and M. Inouye, "Intramolecular chaperones and protein folding," <i>TIBS</i> , (1993), Vol. 18, pp. 442-446.	
CSU	AH	M. Inouye, "Intramolecular Chaperone: The Role of the Pro-Peptide in Protein Folding," <i>Enzyme</i> , (1991), Vol. 45, pp. 314-321.	
CSU	AI	M. Ikehara, et al., "Synthesis of a gene for human growth hormone and its expression in <i>Escherichia coli</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , (Oct. 1984), Vol. 81, pp. 5956-5960.	
CSU	AJ	Watson et al., <i>Recombinant DNA—A Short Course</i> , Scientific American Books, W.H. Freeman Co., NY, (1983), pp. 231-241.	
CSU	AK	Norman and Litwack, "Pancreatic Hormones: Insulin and Glucagon," in <i>Hormones</i> , Academic Press, Inc., NY, (1987), pp 264-317.	
CSU	AL	I. Johnson, "Human Insulin from Recombinant DNA Technology," <i>Science</i> , (Feb. 11, 1983), Vol. 219, pp. 632-637.	
CSU	AM	D. Williams, et al., "Cytoplasmic Inclusion Bodies in <i>Escherichia coli</i> Producing Biosynthetic Human Insulin Proteins," <i>Science</i> , (Feb. 5, 1982), Vol. 215, pp. 687-689.	
CSU	AN	R. Burgess, "Protein Purification," in <i>Protein Engineering</i> , Oxender, D.L., Fox, C.F., Eds.; Alan R. Liss, Inc, NY, (1987), pp. 71-82.	
CSU	AO	R.E. Chance, et al., "The Production of Human Insulin Using Recombinant DNA Technology and a New Chain Combination Procedure," in <i>Peptides: Synthesis-Structure-Function</i> , Pierce Chem. Co., Rockford, IL, (1981), pp. 721-728.	
CSU	AP	B.H. Frank and R.E. Chance, "The Preparation and characterization of human insulin of recombinant DNA origin," in <i>Therapeutic Agents Produced by Genetic Engineering "Quo Vadis?" Symposium</i> , (May 29-30, 1985), Sanoff Group, Toulouse-Labège, France, pp 137-146.	
CSU	AQ	R.E. Chance, et al., "Chemical, Physical, and Biological Properties of Recombinant Human Insulin," in J. L. Gueriguian <i>Insulins, Growth Hormone, and Recombinant DNA Technology</i> , Raven Press, NY, (1981), pp. 71-85.	
CSU	AR	R. D. Johnson, "The Processing of Biomacromolecules: A Challenge for the Eighties," <i>Fluid Phase Equilib.</i> , (1986), 29:109-123.	
CSU	AS	D. V. Goeddel, et al., "Expression in <i>Escherichia coli</i> of chemically synthesized genes for human insulin," <i>Proc. Natl. Acad. Sci. USA</i> , (Jan. 1979), No. 1, pp. 106-110.	

Examiner Signature		Date Considered	2/3/2003
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\*EXAMINER. Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 3

### Complete if Known

Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	Saeed, Christine J.
Attorney Docket Number	020167-000120US

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### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

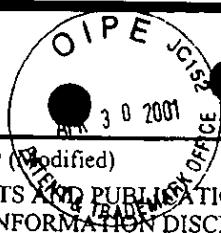
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AT	J. P. Burnett, "Commercial Production of Recombinant DNA-Derived Products," in <i>Experimental Manipulation of Gene Expression</i> , Academic Press, NY, (1983), pp. 259-277.	
	AU	J. Etienne-Decent, "Regulation of Protein Synthesis," in <i>Genetic Biochemistry: From Gene to Protein</i> , Ellis Horwood Limited, Chichester, U.K., (1988), pp. 125-127.	
	AV	S. M. Wheelwright, <i>Protein Purification: Design and Scale up of Downstream Processing</i> , Oxford University Press, NY, (1991), p. 217.	
	AW	B. H. Frank and R. E. Chance, "Two Routes for Producing Human Insulin Utilizing Recombinant DNA Technology," <i>Munch. Med. Wschr.</i> , (1983), Vol. 125, Suppl. 1, pp. S14-S20.	
	AX	E. P. Kroeff, et al, "Production Scale Purification of Biosynthetic Human Insulin by Reversed-Phase High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> , (1989), Vol. 461, pp. 45-61.	
	AY	H. V. Tottrup and S. Carlsen, "A Process for the Production of Human Proinsulin in <i>Saccharomyces cerevisiae</i> ," <i>Biotechnol. Bioeng.</i> , (1990), Vol. 35, pp. 339-348.	
	AZ	L. R. Castellanos-Serra, et al., "Expression and folding of an interleukin-2-proinsulin fusion protein and its conversion into insulin by a single step enzymatic removal of the C-peptide and the N-terminal fused sequence," <i>FEBS Letters</i> , (1996), Vol. 378, pp. 171-176.	
	BA	L. Villa-Komaroff, et al., "A bacterial clone synthesizing proinsulin," <i>Proc. Natl. Acad. Sci. USA</i> , (Aug. 1978), Vol. 75, No. 8, pp. 3727-3731.	
	BB	L. Thim, et al., "Secretion and processing of insulin precursors in yeast," <i>Proc. Natl. Acad. Sci. USA</i> , (Sept. 1986), Vol. 83, pp. 6766-6770.	
	BC	I. V. Diers et al., "Yeast Fermentation Processes for Insulin Production," in Y. H. Chiu <i>Drug Biotechnology Regulations: Scientific Basis and Practices</i> , Marcel Dekker, Inc., NY, (1991), pp. 166-176.	
	BD	M. R. Ladisch and K. L. Kohlmann, "Recombinant Human Insulin," <i>Biotechnol. Prog.</i> , (1992), Vol. 8, pp. 469-478.	

Examiner Signature		Date Considered	3/6/2003
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FORM PTO-1449 (Modified)		Attorney Docket No.: 20167-000120US		Application No.: 09/423,100		
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: Dr. Zhong-Ru Gan				
		Filing Date: October 29, 1999		Group: <del>4798</del> 1647		
Reference Designation		U.S. PATENT DOCUMENTS				Page 1
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
<u>EN</u> AA	6,001,604	12/14/99	Hartman et al.			
<u>EN</u> AB	4,916,212	04/10/90	Markussen et al.			
<u>EN</u> AC	4,342,832	08/03/82	Goeddel et al.			
<u>EN</u> AD	5,254,463	10/19/93	de Boer et al.			
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
<u>EN</u> AE	WO 96/20724	07/11/96	PCT			
<u>EN</u> AF	WO 97/18233	05/22/97	PCT			
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
EXAMINER		<u>G-Mentis</u>		DATE CONSIDERED		<u>3/6/2003</u>

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